UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,260	02/24/2000	Lynn M. Adams	03037.86702	5959

22907 7590 02/14/2003

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/512,260	ADAMS ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

--The MAILING DATE of this communication app ars on the cover sh et with the correspond nce address --

THE REPLY FILED 09 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Elizabeth C. Kemmerer

   Claim(s) allowed: _____.

   Claim(s) objected to: 7.

   Claim(s) rejected: 1-6.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE: Claims 1 and 2 , if entered, would be rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite "have a sequence as shown in SEQ ID NO:1" and "has a 22 amino acid sequence as shown in SEQ ID NO:2" respectively. The claims are indefinite because it is unclear if "have" and "has" is open or closed language. The metes and bounds of the claims cannot be determined.

Continuation of 5. does NOT place the application in condition for allowance because: if the claims were entered, claims 1 and 2 stand rejected under 35 USC 102(e) as being anticipated by Tsui et al., US Patent No. 5,776,677. The rejections are maintained for reason of record. Applicant states that claim 1 recites a portion of the CFTR polypeptide that consists of between 18 and 100 amino acid residues. Applicant states that this is closed language which requires a maximum of 100 amino acids of CFTR and that claim 2 is dependent on claim 1 and therefore also contains this limitation. This is not found persuasive. Applicant recites "consists" but also recites "between 18 and 100 amino acids". This is not closed language. The problem is that the claim is to a polypeptide "comprising" the portion that reads on full-lenth. The claim as recited does not solely require a maximum of 100 amino acids of CFTR. The claim is drawn to SEQ ID NO:1 which is only 18 amino acids long. Thus the polypeptide can have a minimum of 18 amino acids and a maximum of 100 amino acids (between 18 and 100 amino acids) from CFTR. 18 amino acids residues of the CFTR portion has to have the sequence as shown in SEQ ID NO:1. SEQ ID NO:1 is 18 amino acids long. Tsui teaches a sequence which is 100% identical to SEQ ID NO:1. Tsui also teaches a sequence which is 100% identical to SEQ ID NO:2.

If the claims were entered, claims 3-6 stand rejected under 35 USC 103(a) as being unpatentable over Tsui et al., US Patent No. 5,776,677 in view of Welsh et al., WO 95/25796 (IDS, Paper No. 4) and Langel et al., US Patent No. 6,025,140. The rejections are maintained for reasons of record. Applicant incorporates their response to the rejection under 35 USC 102(e) in response to the rejection under 35 USC 103(a). The rejection is based on Tsui's teachings of sequences comprising SEQ ID NO:1 and SEQ ID NO:2. Applicants arguments have been fully considered but are not found to persuasive for the reasons discussed above in the maintained rejection in 35 USC 102(e). Based on the teachings of Tsui, it would be obvious to modify the instant invention based on Welsh's teachings regarding truncated CFTR polypeptides and Langel's teachings of membrane-penetrating peptides sequences which are 100% identical to SEQ ID NO:4 and SEQ ID NO:5.

Continuation of 10. Other: Applicant requests clarification of the status of claim 7. The rejection of claim 7 under 112, first paragraph as set forth in the previous Office Action (07 May 2002, Paper No. 10) was withdrawn (07 August 2002, Paper No. 11). However, if the amendment was entered, claim 7 would be objected to for depending from a rejected claim (claim 1).